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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,987	06/08/2001	Robert M. Townsend	D0009NP/30436.53USU1	1712
23914	7590 01/23/2003			
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			EXAMINER	
			GAMBEL, PHILLIP	
			ART UNIT	PAPER NUMBER
ridite Lion,	113 005-5-000		1644	
			DATE MAILED: 01/23/2003	14

Please find below and/or attached an Office communication concerning this application or proceeding.

·	Application No.	Applicant(s)			
	09/877987	Townsend			
Office Action Summary	Examiner	Art Unit			
• •	GAMBEL	1644			
- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -					
Period for Reply		`			
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1:  - state SX (8) MONTHS from the malling date of this communication.  - if the period for reply specified above is less than thirty (30) days, a repl.  - If NO period for reply specified above, the maximum statutory period of Tailure to reply within the set or extended period for reply will, by statute,	38(a). In no event, however, may a reply be tir within the statutory minimum of thirty (30) day fill apply and will expire SIX (8) MONTHS from	s will be considered timely.			
<ul> <li>Any reply received by the Office later then three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>					
Status					
1) Responsive to communication(s) filed on	relor				
2a) This action is FINAL. 2b) Th	is action is non-final.	k.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453, O.G. 213.  Disposition of Claims					
4) Claim(s) is/are pending in the application. 1 - 36					
4a) Of the above claim(s) is/are withdrawn from consideration. 10, 19 - 36					
5) Claim(s) is/are allowed.					
6) Claim(s)is/are rejected.	·				
7) Cláim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/o	r election requirement. 1-9	11-18			
Application Papers					
9)☐ The specification is objected to by the Examine					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12)☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
<ol> <li>Certified copies of the priority documents</li> </ol>	s have been received.				
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
<ul> <li>a) The translation of the foreign language provisional application has been received.</li> <li>15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>					
Attachment(s)	30	No.			
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449) Paper No(s)		/ (PTO-413) Paper No(s) Patent Application (PTO-152)			
S. Petent and Trademark Office TO-326 (Rev. 04-01) Office Act	tion Summary	Part of Paper No. 14			

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## **DETAILED ACTION**

1. Applicant's amendment, filed 10/22/02 (Paper No. 11), has been entered.

Claims 11, 28 and 36 have been amended.

Formal drawings, filed 10/22/02 (Paper No. 12), comply with 37 CFR 1.84.

2. Applicant's election with traverse of Group I and the species of agent one is soluble CTLA4, the species of agent two is anti-CD154 antibody and the species of agent 3 is anti-LFA-1 antibody in Paper No. 11 is acknowledged. The traversal is on the ground(s) that Group I-II are classified in the same classes and separate prosecution of the these claims would be unnecessarily duplicative. This is not found persuasive because of the inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed (see MPEP 806.05-806.05(I))) for the reasons of record set forth in the Restriction Requirement (Paper No. 10). Also, the inventions require non-coextensive searches whether or not the classifications alone are coextensive.

It is noted that claim 36 is in the non-elected Group II.

Therefore, claims 1-9 and 11-18 are under consideration in the instant application rather than applicant's assertions that the elected invention read on claims 1-9, 11-26, 28-34 and 36.

Claims 10, and 19-36 are withdrawn from consideration as being drawn to the nonelected invention and species.

3. Upon a review of the instant, the following species election is set forth as it reads on the elected invention and species. The examiner apologizes for any inconvenience to applicant in this matter.

This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the targeted disease or condition is selected from transplant rejection or one of the diseases set forth in claim 30.

These species are distinct because their etiologies and therapeutic endpoints are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic, for example.

4. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

- 5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 7. In the interest of compact prosecution, applicant is invited to provide evidence or meet the enablement requirements under 35 USC 112, first paragraph, for the deposit of the pertinent cell lines / hybridomas which produce the claimed antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that <u>all</u> restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

It is noted that the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to the claimed antibodies may have been satisfied via issued U.S. Patents. Applicant is reminded that mere disclosure of an antibody / hybridoma in a U.S. Patent does not necessarily satisfy the requirements under 35 USC 112, first paragraph. See MPEP 24-04.01.

Applicant is invited to provide evidence to support the deposit requirement for the claimed antibodies have been satisfied, at least with respect to the elected invention. The examiner appreciates the efforts of applicant in this matter.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD. Primary Examiner Technology Center 1600 January 17, 2002